K070494

SECTION 4: EXECUTIVE SUMMARY

MAY - 1 2007

Device Description

The device is designed and manufactured to emit a high intensity pulsed light applied to the patient's skin. The light is emitted by a quick discharge of capacitors on a xenon flash lamp with a high energy. The lamp delivers a wavelength in the band of 390-1200nm.

The three principal parts of this system are:

1. The **Principal Unit** which contain all circuitry to control the device. This unit is composed of:
   - Power Supply section which allows the necessary power supply to the system (power supply socket, main switch, power supply transformer, and the Ac/Dc the power supply converter, for PC board).
   - Control section is composed of control board PC board and human interface system (TFT display)
   - Power section allows generating and storing the energy used to generate the output light. It is composed of power board and power capacitors.
2. The **Handpiece** contains circuitry to control the Lamp & Filter group. It is connected with the principal unit with a removable cable
3. The **Lamp & Filter group** is a removable box that contains Xenon Flash Lamp and Filter mounted on to the handpiece.

Intended Use

This product is intended for dermatological use by physicians and healthcare professionals for the following:

- Removal of unwanted hair in all skin types (from 570 to 1200nm filters)
- Treatment of vascular and benign pigmented lesions, cutaneous lesions including warts, scars, striae and facial and leg veins (from 550 to 1200nm filter).
- Treatment of Acne (from 390 to 1200nm filter)

Device Description

The device is designed and manufactured to emit a high intensity pulsed light applied to the patient's skin. The light is emitted by a quick discharge of some capacitors on a xenon flash lamp with a high energy. The lamp delivers a wavelength in the band of 390-1200nm. The three principal parts of the system include:

- The **Principal Unit,** that contain all circuitry to control the device as the capacitor charge system, the microcontroller and all the electronic parts; the
- The **Handpiece**, that contain part of circuitry to control the Lamp & Filter group;
- The **Lamp & Filter group**, a removable box that contain Xenon Flash Lamp and Filter mounted on to the handpiece.

Intended Use

This product is intended for dermatological use by physicians and healthcare professionals for the following:

- Removal of unwanted hair in all skin types (from 570 to 1200nm filter)
- Treatment of vascular and benign pigmented lesions, cutaneous lesions including warts, scars, striae and facial and leg veins (from 550 to 1200nm filter).
- Treatment of Acne (from 390 to1200nm filter)

Comparison to Predicate Devices

The intended use and the technological characteristics of the Espansione Marketing EPI-C PLUS and its predicate devices are very similar as explained in section 6 of this submission. Espansione Marketing EPI-C PLUS is substantially equivalent to its predicate device cited above, and raises no new safety and/or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Espansione Marketing SPA
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Guido Bonapace
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40068 – San Lazzaro di Savena
Bologna, Italy

MAY - 1 2007

Re: K070494
Trade/Device Name: EPI-C PLUS
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 15, 2007
Received: February 20, 2007

Dear Guido Bonapace:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

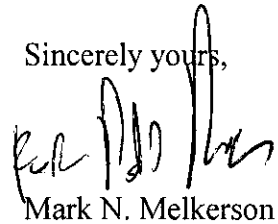
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K 070494

Device Name: EPI-C PLUS

Indications for Use:

This product is intended for dermatological use by physicians and healthcare professionals for the following:

- Removal of unwanted hair in all skin types (from 570- to 1200nm filter)
- Treatment of vascular and benign pigmented lesions, cutaneous lesions including warts, scars, striae and facial and leg veins (from 550 to1200nm filter).
- Treatment of Acne (from 390 to 1200nm filter)

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[**CERTIFICATION IS TO BE ON COMPANY LETTERHEAD, SIGNED AND DATED BY THE RESPONSIBLE INDIVIDUAL**]

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070494